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13. ABSTRACT (Maximum 200 Words) This study focuses on quality of life among women with ovarian cancer. Our primary objective is to identify the issues that are of greatest concern to women in each of three treatment stages: newly diagnosed with ovarian cancer, in-treatment, and post-treatment. A longitudinal, repeated measures design is used to assess changes in problem areas and quality of life from diagnosis to recurrence among women newly diagnosed with ovarian cancer. The CARES-SF and FACT-O questionnaires are administered to participants following diagnosis and prior to chemotherapy, during chemotherapy, following chemotherapy, and after recurrence. Data collection for the study will last 28 months (patient accrual will last 25 months and follow-up will continue an additional 3 months). Data for the study will be collected through in-person interviews, and mailed questionnaires from women treated at the Wake Forest University Baptist Medical Center (WFUBMC).				
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Appendix A: Study Forms

PART I - INTRODUCTION

This study focuses on quality of life among women with ovarian cancer. The primary objective is to identify the issues that are of greatest concern to women in each of three treatment stages: newly diagnosed with ovarian cancer, in-treatment, and post-treatment. A longitudinal, repeated measures design is being used to assess changes in problem areas and quality of life from diagnosis to recurrence among women newly diagnosed with ovarian cancer. The CARES-SF and FACT-O questionnaires are administered to participants following diagnosis and prior to chemotherapy, during chemotherapy, following chemotherapy, and after recurrence.

Data collection for the study will last 28 months (patient accrual will last 25 months and follow-up will continue an additional 3 months). Data for the study are collected through in-person interviews, and mailed questionnaires from women treated at the Wake Forest University Baptist Medical Center (WFUBMC).

Secondary objectives are of the study: 1) to assess changes in quality of life (as quantified by the FACT-O questionnaire) across the different stages of care, 2) to determine which patient characteristics are predictive of quality of life at each treatment stage, 3) to determine which patient characteristics are predictive of changes in quality of life across the different treatment stages, and 4) to obtain pilot data on problems and quality of life issues for women who experience a recurrence.

PART II – BODY: STATEMENT OF WORK

The primary activities during this first year of the study have been to obtain Human Subjects Protection approval from the Department of Defense, finalize study forms, and pilot the study. The tasks described in the original statement of work have not changed. However, time involved in obtaining Human Subjects approval from the Department of Defense was not included as part of the original timeline. This approval has taken an enormous amount of time and has essentially moved the timeline back over a year. This approval was obtained on 8/8/02. However, as we were reviewing the protocol and forms, we felt that we needed to modify the procedure at baseline (so that the questionnaires could be completed by patients at home) and to replace the coping form with a shorter form. These modifications were submitted to Dr. Pranulis in the Office of Human Subjects Protection on 9/26/02 and approved by the WFUSM IRB on 10/4/02. We are awaiting DOD approval for these modifications.

Task 1: Develop research protocol (months 1-2)

a. Compile open-ended questions, relevant questionnaires, and sociodemographics in an interview format

The questionnaires have been compiled and approved by the WFUSM IRB. As mentioned above, we have requested a change in one of the questionnaires. We have attached a copy of the questionnaires in Appendix A.

b. Train study interviewer

The study interviewer has been hired and trained. The project director has also been hired and trained to serve as a back-up interviewer.

c. Pilot test interview with patients

We have not had the opportunity to pilot the interview as no subjects have entered the study.

d. Finalize questionnaire based on pilot

Task 2: Develop data management system (months 1-2)

We are currently in the process of working on the following tasks. They will not be completed until the questionnaires and protocol are finalized.

- a. Develop data management requirements
- b. Develop reporting requirements
- c. Develop contact record
- d. Train research staff to use DMS

Task 3: Identify, recruit, and interview patients who meet eligibility criteria (months 3-27)

- a. Identify eligible patients
- b. Recruit and interview patients
- c. Conduct quality control of interviews (ongoing)
- d. Develop data entry system
- e. Transcribe and code open-ended interviews (ongoing)
- f. Abstract clinical data from charts (ongoing)
- g. Data entry of questionnaires (ongoing)

Task 4: Ongoing Follow-up of Patients (months 6-30)

- a. Track women previously interviewed
- b. Interview women at appropriate treatment stages
- c. Interview recurrent cases

Task 5: Data analysis and report writing (months 31-36)

- a. Transfer data into SAS
- b. Clean data and generate codebooks
- c. Analyze data from interviews

- d. Present results at professional meeting
- e. Prepare initial manuscripts

Task 6: Develop interventions that can be tested in future research (month 36)

- a. Review findings and develop ideas for interventions
- b. Plan interventions for future trials

PART III - KEY RESEARCH ACCOMPLISHMENTS

- Finalization of study forms
- Obtaining human subjects protection approval

PART IV - REPORTABLE OUTCOMES

None

PART V - CONCLUSIONS

This section is not applicable at this point.

PART VI - REFERENCES

Not applicable

APPENDICES

Attached are the Study Forms.

APPENDIX A

**SAMPLE
STUDY FORMS**

Interviewer _____

Respondent ID#

--	--	--	--

Date:

--	--

Month

--	--

Day

2	0	0	
---	---	---	--

Year

Ovarian Cancer and Quality of Life Study

Baseline Survey

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A. QUALITY OF LIFE

The first set of questions is about your current general quality of life.

- A.1. Here is a picture of a stepladder. The top of the ladder represents the best possible life for you. The bottom of the ladder represents the worst possible life for you. On which of these 10 steps of the ladder do you feel you personally stand at the present time?

(Circle one number from 1 to 10)

	10 Best Possible Life
	9
	8
	7
	6
	5
	4
	3
	2
	1 Worst Possible Life

- A.2. On a 7-point scale where "1" indicates complete dissatisfaction and "7" indicates complete satisfaction, which number comes closest to how you feel about your life as a whole these days?

(Circle one number from 1 to 7)

1	2	3	4	5	6	7
Complete Dissatisfaction						Complete Satisfaction

- A. 3. Finally, please mark with an "X" the appropriate place within the bar below to indicate your rating of the quality of your life in the past 2 weeks:

Lowest
Possible
Quality

--

Highest
Possible
Quality

B. FACT – O (Version 4)

Below is a list of statements that other people with your illness have said are important. Please circle the number that best describes how true each statement has been for you during the past 7 days.

<u>Physical Well-Being</u>	Not At All	A Little Bit	Some- what	Quite a bit	Very Much
B.1. I have a lack of energy	0	1	2	3	4
B.2. I have nausea	0	1	2	3	4
B.3. Because of my physical condition, I have trouble meeting the needs of my family.....	0	1	2	3	4
B.4. I have pain	0	1	2	3	4
B.5. I am bothered by side effects of treatment.....	0	1	2	3	4
B.6. I feel ill	0	1	2	3	4
B.7. I am forced to spend time in bed.	0	1	2	3	4

Social/Family Well-Being

B.8. I feel close to my friends	0	1	2	3	4
B.9. I get emotional support from my family	0	1	2	3	4
B.10. I get support from my friends.....	0	1	2	3	4
B.11. My family has accepted my illness	0	1	2	3	4
B.12. I am satisfied with family communication about my illness.....	0	1	2	3	4
B.13. I feel close to my partner (or the person who is my main support).....	0	1	2	3	4

Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box ☐ and go to the next section.

B.14. I was satisfied with my sex life	0	1	2	3	4
--	---	---	---	---	---

<u>Emotional Well-Being</u>	Not At All	A Little Bit	Some- what	Quite a bit	Very Much
B.15. I feel sad	0	1	2	3	4
B.16. I am satisfied with how I am coping with my illness	0	1	2	3	4
B.17. I am losing hope in the fight against my illness.....	0	1	2	3	4
B.18. I feel nervous	0	1	2	3	4
B.19. I worry about dying	0	1	2	3	4
B.20. I worry that my condition will get worse.....	0	1	2	3	4

Functional Well-Being

B.21. I am able to work (include work at home).....	0	1	2	3	4
B.22. My work (include work at home) is fulfilling.....	0	1	2	3	4
B.23. I am able to enjoy life.....	0	1	2	3	4
B.24. I have accepted my illness.....	0	1	2	3	4
B.25. I am sleeping well	0	1	2	3	4
B.26. I am enjoying the things I usually do for fun.....	0	1	2	3	4
B.27. I am content with the quality of my life right now....	0	1	2	3	4

Additional Concerns

B.28. I have swelling in my stomach area	0	1	2	3	4
B.29. I am losing weight	0	1	2	3	4
B.30. I have control of my bowels.....	0	1	2	3	4
B.31. I have been vomiting	0	1	2	3	4
B.32. I am bothered by hair loss	0	1	2	3	4
B.33. I have a good appetite.....	0	1	2	3	4
B.34. I like the appearance of my body	0	1	2	3	4
B.35. I am able to get around by myself.....	0	1	2	3	4
B.36. I am able to feel like a woman	0	1	2	3	4
B.37. I have cramps in my stomach area	0	1	2	3	4
B.38. I am interested in sex.....	0	1	2	3	4
B.39. I have concerns about my ability to have children...	0	1	2	3	4

C. PROBLEM STATEMENTS

Below is a list of Problem Statements that describe situations and experiences of individuals who have or have had cancer. Read each statement and circle the number that best describes how much each statement applies to you during the past week, including today. Some sections will not apply to you. Please skip these sections and proceed to the next one as directed.

Please circle one number on each line.

How much does it apply to you?	<u>Not at all</u>	<u>A little</u>	<u>A fair amount</u>	<u>Much</u>	<u>Very Much</u>
C.1. I have difficulty bending or lifting	0	1	2	3	4
C.2. I do not have the energy I used to	0	1	2	3	4
C.3. I have difficulty doing household chores	0	1	2	3	4
C.4. I have difficulty bathing, brushing my teeth, or grooming myself	0	1	2	3	4
C.5. I have difficulty planning activities because of the cancer or its treatments	0	1	2	3	4
C.6. I cannot gain weight.....	0	1	2	3	4
C.7. I find food unappealing	0	1	2	3	4
C.8. I find that cancer or its treatments interfere with my ability to work.....	0	1	2	3	4
C.9. I frequently have pain	0	1	2	3	4
C.10. I have chronic pain from scars and surgery	0	1	2	3	4
C.11. I have pain that is not controlled by pain medication	0	1	2	3	4
C.12. I have pain that is controlled by pain medication	0	1	2	3	4
C.13. I find that my clothes do not fit.....	0	1	2	3	4
C.14. I find that doctors don't explain what they are doing to me	0	1	2	3	4
C.15. I have difficulty asking doctors questions.....	0	1	2	3	4

	<u>Not at all</u>	<u>A little</u>	<u>A fair amount</u>	<u>Much</u>	<u>Very Much</u>
C.16. I have difficulty understanding what the doctors tell me about the cancer or its treatments	0	1	2	3	4
C.17. I would like to have more control over what the doctors do to me.....	0	1	2	3	4
C.18. I am uncomfortable with the changes in my body	0	1	2	3	4
C.19. I frequently feel anxious	0	1	2	3	4
C.20. I have difficulty sleeping.....	0	1	2	3	4
C.21. I have difficulty concentrating	0	1	2	3	4
C.22. I have difficulty asking friends or relatives to do things for me	0	1	2	3	4
C.23. I have difficulty telling my friends or relatives about the cancer	0	1	2	3	4
C.25. I find that my friends or relatives tell me I'm looking well when I'm not	0	1	2	3	4
C.26. I find that my friends or relatives do not visit often enough	0	1	2	3	4
C.27. I find that friends or relatives have difficulty talking with me about my illness	0	1	2	3	4
C.28. I have difficulty telling my friends or relatives to come over less often	0	1	2	3	4
C.29. I have difficulty telling my friends or relatives to leave when I do not feel well.....	0	1	2	3	4
C.30. I have difficulty asking my friends or relatives to do something fun with me	0	1	2	3	4
C.31. I do not know what to say to my friends or relatives..	0	1	2	3	4
C.32. I worry about whether my treatments are working	0	1	2	3	4
C.33. I worry about how my family will manage if I die	0	1	2	3	4

	<u>Not at all</u>	<u>A little</u>	<u>A fair amount</u>	<u>Much</u>	<u>Very Much</u>
C.34. I have difficulty asking my friends or relatives to come over more often	0	1	2	3	4
C.35. I become nervous when I am waiting to see the doctor		0	1	2	3 4
C.36. I become nervous when I get my blood drawn	0	1	2	3	4
C.37. I worry about whether the cancer is progressing	0	1	2	3	4
C.38. I worry about whether my treatments are working	0	1	2	3	4
C.39. I worry about how my family will manage if I die	0	1	2	3	4
C.40. I do not feel sexually attractive	0	1	2	3	4
C.41. I am not interested in having sex	0	1	2	3	4
C.42. I sometimes don't follow my doctor's instructions	0	1	2	3	4
C.43. I have financial problems	0	1	2	3	4
C.44. I have insurance problems	0	1	2	3	4
C.45. I have difficulty with transportation to and from my medical appointments and/or other places	0	1	2	3	4
C.46. I am gaining too much weight	0	1	2	3	4
C.47. I have frequent episodes of diarrhea	0	1	2	3	4
C.48. I have times when I do not have control of my bladder...	0	1	2	3	4

Do you have children?

Yes

No

If **No**, skip to question C.50.

C.49. I have difficulty helping my children cope with my illness	0	1	2	3	4
---	---	---	---	---	---

		<u>Not at all</u>	<u>A little</u>	<u>A fair amount</u>	<u>Much</u>	<u>Very Much</u>
Are you working or have you been employed during the last month?	Yes No					

If No, skip to question C.53.

C.50. I have difficulty talking to the people who work with me about my cancer	0	1	2	3	4
C.51. I have difficulty asking for time off from work for medical treatments	0	1	2	3	4
C.52. I am worried about being fired.....	0	1	2	3	4

Did you look for work during the past month?	Yes No
--	-------------

If No, skip to question C.54.

C.53. I have difficulty finding a new job since I have had cancer	0	1	2	3	4
---	---	---	---	---	---

Have you attempted sexual intercourse since your cancer diagnosis?	Yes No
--	-------------

If No, skip to question C.55.

C.54. I find that the frequency of sexual intercourse has decreased	0	1	2	3	4
---	---	---	---	---	---

Are you married or in a significant relationship?	Yes No
---	-------------

If No, skip to question C.61.

C.55. My partner and I have difficulty talking about our feelings	0	1	2	3	4
C.56. My partner and I have difficulty talking about wills and financial arrangements	0	1	2	3	4
C.57. I do not feel like embracing, kissing, or caressing my partner	0	1	2	3	4

	<u>Not at all</u>	<u>A little</u>	<u>A fair amount</u>	<u>Much</u>	<u>Very Much</u>
C.58. My partner and I are not getting along as well as we usually to	0	1	2	3	4
C.59. My partner spends too much time taking care of me..	0	1	2	3	4
C.60. I have difficulty asking my partner to take care of me	0	1	2	3	4

Are you single and not in a
significant relationship:

Yes No

If No, skip to question C.63.

C.61. I have difficulty initiating contact with potential dates	0	1	2	3	4
C.62 I have difficulty telling a date about the cancer and its treatments	0	1	2	3	4

Have you had chemotherapy
treatments in the last month?

Yes No

If No, skip to question C.71.

C.63 I become nervous when I get chemotherapy.....	0	1	2	3	4
C.64. I become nauseated during and/or before chemotherapy.....	0	1	2	3	4
C.65. I feel nauseated after I receive chemotherapy.....	0	1	2	3	4
C.66. I vomit after chemotherapy	0	1	2	3	4
C.67. I have other side effects after chemotherapy	0	1	2	3	4
C.68. I feel sick when I think about my chemotherapy	0	1	2	3	4
C.69. I feel tired after my chemotherapy	0	1	2	3	4
C.70. I have lost my hair and/or it is growing back slowly because of chemotherapy	0	1	2	3	4

D. OPTIMISM – LIFE ORIENTATION TEST

The following statements have to do with your general outlook on life. To what extent do you agree or disagree with the following statements?

Please circle one number on each line)

	Agree a lot	Agree a little	Neither agree nor disagree	Disagree a little	Disagree alot
D.1. In uncertain times I usually expect the best	1	2	3	4	5
D.2. It's easy for me to relax.....	1	2	3	4	5
D.3. If something can go wrong for me, it will.....	1	2	3	4	5
D.4. I'm always optimistic about my future	1	2	3	4	5
D.5. I enjoy my friends a lot	1	2	3	4	5
D. 6. It's important for me to keep busy	1	2	3	4	5
D.7. You hardly ever expect things to go my way...	1	2	3	4	5
D.8. I don't get upset too easily	1	2	3	4	5
D.9. I rarely count on good things happening to me	1	2	3	4	5
D.10. Overall, I expect more good things to happen to me than bad	1	2	3	4	5

E. WAYS OF COPING

These items deal with ways you've been coping with your diagnosis of cancer. Obviously, different people deal with things in different ways, but we are interested in how you've tried to deal with your illness.

Each item says something about a particular way of coping. We want to know to what extent you've been doing what the item says--how much or how frequently. Do not answer on the basis of whether it seems to be working or not--just whether or not you're doing it. Use these response choices. Try to rate each item separately in your mind from the others. Make your answers as true **FOR YOU** as you can.

- 1 = I haven't been doing this at all
- 2 = I've been doing this a little bit
- 3 = I've been doing this a medium amount
- 4 = I've been doing this a lot

	Not doing at all	Doing a little bit	Doing a medium amount	Doing a lot
E.1. I've been turning to work or other activities to take my mind off things.....	1	2	3	4
E.2. I've been concentrating my efforts on doing something about the situation I'm in.....	1	2	3	4
E.3. I've been saying to myself "this isn't real.".....	1	2	3	4
E.4. I've been using alcohol or other drugs to make myself feel better.....	1	2	3	4
E.5. I've been getting emotional support from others.....	1	2	3	4
E.6. I've been giving up trying to deal with it.....	1	2	3	4
E.7. I've been taking action to try to make the situation feel better.	1	2	3	4
E.8. I've been refusing to believe that it has happened.....	1	2	3	4
E.9. I've been saying things to let my unpleasant feelings escape...	1	2	3	4
E.10. I've been getting help and advice from other people.....	1	2	3	4
E.11. I've been using alcohol or other drugs to help me get through it.	1	2	3	4
E.12. I've been trying to see it in a different light, to make it seem more positive.....	1	2	3	4

	Not doing at all	Doing a little bit	Doing a medium amount	Doing a lot
E.13. I've been criticizing myself.....	1	2	3	4
E.14. I've been trying to come up with a strategy about what to do.	1	2	3	4
E.15. I've been getting comfort and understanding from someone..	1	2	3	4
E.16. I've been giving up the attempt to cope.....	1	2	3	4
E.17. I've been looking for something good in what is happening...	1	2	3	4
E.18. I've been making jokes about it.....	1	2	3	4
E.19. I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.....	1	2	3	4
E.20. I've been accepting the reality of the fact that it has happened.	1	2	3	4
E.21. I've been expressing my negative feelings.....	1	2	3	4
E.22. I've been trying to find comfort in my religion or spiritual beliefs.....	1	2	3	4
E.23. I've been trying to get advice or help from other people about what to do.....	1	2	3	4
E.24. I've been learning to live with it.....	1	2	3	4
E.25. I've been thinking hard about what steps to take.....	1	2	3	4
E.26. I've been blaming myself for things that happened.....	1	2	3	4
E.27. I've been praying or meditating.....	1	2	3	4
E.28. I've been making fun of the situation.....	1	2	3	4
E.29. I've tried to keep my feelings to myself.....	1	2	3	4
E.30. I've kept others from knowing how bad things were.....	1	2	3	4
E.31. I've wished that the situation would go away or somehow be over with.....	1	2	3	4
E.32. I've had fantasies or wishes about how things might turn out.	1	2	3	4

F. RAND Social Support Scale

People sometimes look to others for companionship, assistance, or other types of support. Next are some questions about support that may be available to you. During the past 4 weeks, how much was someone available to help you if you needed and wanted help (for example, if you needed someone to talk to or if you needed help with daily chores)?

Please circle one number on each line.

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
F.1. Someone to help you if you were confined to bed	1	2	3	4	5
F.2. Someone you can count on to listen to you when you need to talk	1	2	3	4	5
F.3. Someone to give you good advice about a crisis	1	2	3	4	5
F.4. Someone to take you to the doctor if you needed it...	1	2	3	4	5
F.6. Someone to have a good time with	1	2	3	4	5
F.7. Someone to give you information to help you understand a situation	1	2	3	4	5
F.8. Someone to confide in or talk about yourself and your problems	1	2	3	4	5
F.9. Someone who hugs you	1	2	3	4	5
F.10. Someone to get together with for relaxation	1	2	3	4	5
F.11. Someone to prepare your meals if you were unable to yourself.....	1	2	3	4	5
F.12. Someone whose advice you really want	1	2	3	4	5
F.13. Someone to do things with to help you get your mind off things.....	1	2	3	4	5
F.14. Someone to help you with your daily chores if you were sick.....	1	2	3	4	5
F.15. Someone to share your most private worries and fears with.....	1	2	3	4	5

None of the time	A little of the time	Some of the time	Most of the time	All of the time
---------------------	-------------------------	---------------------	---------------------	--------------------

- | | | | | | |
|--|---|---|---|---|---|
| F.16. Someone to turn to for suggestions about how to
deal with a personal problem..... | 1 | 2 | 3 | 4 | 5 |
| F.17. Someone to do something enjoyable with..... | 1 | 2 | 3 | 4 | 5 |
| F.18. Someone who understands your problems..... | 1 | 2 | 3 | 4 | 5 |
| F.19. Someone to love and make you feel wanted..... | 1 | 2 | 3 | 4 | 5 |

G. DEMOGRAPHIC FORM

The following questions are about your background. This information will help us describe, in general terms, the women who are participating in the study.

Please check the appropriate box for each question.

G.1. What is your marital status?

- ☐ Never married
- ☐ Presently married
- ☐ Living in a marriage-like relationship
- ☐ Divorced or separated
- ☐ Widowed

G.2. What category below best describes your racial/ethnic background? If you are of mixed racial/ethnic background, choose the category with which you most closely identify yourself.

- ☐ American Indian or Alaskan Native (Not Hispanic)
- ☐ Asian or Pacific Islander
- ☐ Black or African American (Not Hispanic)
- ☐ Hispanic
- ☐ White (Not Hispanic)

G.3. What is your date of birth?

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Month

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Day

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Year

G.4. Which category below best describes the highest level of formal education you have completed? Check the one best answer.

- ☐ No formal education
- ☐ Grade school (1st through 8th grade)
- ☐ Some high school (9th through 11th grade)
- ☐ High school diploma or G.E.D.
- ☐ Business or vocational training school after high school graduation
- ☐ Some college (but a college degree was not obtained)
- ☐ Associate Degree (A.D. or A.A.)
- ☐ College graduate or Baccalaureate Degree (B.A. or B.S.)
- ☐ Some college or professional school after college graduation
- ☐ Master's Degree
- ☐ Doctoral Degree (Ph.D., M.D., J.D., D.D.S., etc.)

G.5. How hard is it for you to pay for the very basics like food, housing, medical care, and heating? Would you say it is very hard, somewhat hard, or not very hard at all?
Check one box below.

- ☐ Very hard
- ☐ Somewhat hard
- ☐ Not very hard at all

G.6. What was your total family income (before taxes) from all sources last year? Check one box below. This information is important for describing the women in the study as a group and is kept strictly confidential.

- ☐ Less than \$10,000
- ☐ \$10,000 to \$19,999

- ☐ \$20,000 to \$34,999
- ☐ \$35,000 to \$49,999
- ☐ \$50,000 to \$74,999
- ☐ \$75,000 to \$100,000
- ☐ More than \$100,000

G.7. What is your current employment status? *(Check the box that describes you.)*

- ☐ Unemployed/Looking for work
- ☐ Retired
- ☐ Full-time Homemaker
- ☐ Employed - full-time
- ☐ Employed - part-time
- ☐ Disabled, unable to work
- ☐ Student
- ☐ Other (Please list): _____

G.8. Including yourself, what is the total number of persons who are currently living in your household?

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Persons

G.9. Including all the people in your household, how many of them do you provide partial or total care for?

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Persons

G.10. Including all the people in your household, how many people are able to provide partial or total care for you?

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Persons